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10/061,960

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Marco Falcioni

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EXAMINER

CLOW, LORI A

ART UNIT

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1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--|--|--|
| Office Action Summary | Application No. 10/061,960 | Applicant(s) FALCIONI ET AL. | |
| | Examiner Lori A. Clow, Ph.D. | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-13 and 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>1/16/07; 7/03/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 3 July 2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-24 are currently pending. Claims 4, 5, 14, and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 14 October 2005.

Claims 1-3, 6-13, 16-24 are examined herein.

Information Disclosure Statement

The Information Disclosure Statement filed 3 July 2007 has been considered. A signed copy of PTO Form 1449 is included with this Office Action.

The Information Disclosure Statement filed 16 January 2007 has been considered, in as much as Applicant has admitted that the references are prior art. Certain references, however, do not contain publication dates and are therefore not in compliance with the requirements for IDS submission. The IDS is therefore improper and until such time as Applicant provides a publication date, the lined through references are not eligible for printing on the face of a US Patent.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 6-11, 16-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is necessitated by amendment to the claims. Specifically, Applicant has amended claim 1 to read “storing the library design in a computer memory”.

The computer-implemented method of the instant claims is directed to a method for generating a library design for a set of experiments. The claims, as a whole, do not produce a result which is concrete, tangible, and useful. The claims merely encompass *in silico* manipulations with no **specific** output that meets the concrete, tangible, and useful criteria. The method of merely defining a library, defining a plurality of sources, receiving inputs, generating electronic data, and storing a library does not set forth a **specific** outcome such that the steps of the method produce a result that is immediately concrete, tangible, and useful. The claims must, **as a whole**, satisfy section 101 and must be for practical application, which can be defined as:

1. The claimed invention “transforms” and article or physical object to a different state or thing. *[The claimed invention in the instant case does not **transform** any physical object or article. The generating a design step does not meet the criteria a physical transformation of the instant method steps.]*
2. The claimed invention otherwise produces a useful, concrete, and tangible result, based upon various factors (see below) *[The claimed invention in the instant application does not produce a concrete, tangible, and useful result].*

It is further noted that “the focus of the inquiry is whether the claim, considered as a whole, constitutes ‘a practical application of an abstract idea.’” State Street, 149 F.3d at 1373, 47 USPQ2d at 1600. Thus, the question of whether a claim encompasses statutory subject matter should not focus on which category of subject matter a claim is directed (e.g. process or machine), “but rather on the essential characteristics of the subject matter, in particular its practical utility.” State Street, 149 F.3d at 1375, 47 USPQ2d at 1602; see also AT&T, 172 F.3d at 1360, 50 USPQ2d at 1453.

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” (1) “USEFUL RESULT” For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). (2) “TANGIBLE RESULT” The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection.” Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is “abstract.” (3) “CONCRETE RESULT” Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable.

In response to Applicant's arguments:

It is maintained that the computer program product fails to provide statutory subject matter. For instance, the computer-readable medium is not limited to be just a physical medium and could constitute a signal, which is non-statutory. Further, the execution of instructions does not provide a transformation of matter nor does it provide a concrete, tangible or useful result. Merely storing something in a computer memory does not provide a tangible output, for example, to a user and the claim is non-statutory.

This rejection could be overcome by amending the claims to recite that a result of the method is "displayed" or "outputted" (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay), if such is supported in the Specification as originally filed. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

Applicant is invited to view the following web site for the text of the new Interim Guideline guidelines of November 2005:

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-13, and 16-24 remain rejected under 35 U.S.C. 102(b) as being rejected by WO 00/23921 (27 April 2000; Lacy et al.; PTO 1449 Reference), for the reasons set forth in the previous Office Action and re-iterated below. Newly added claims 23 and 24 are rejected as necessitated by amendment.

The instant claims are drawn to a computer-implemented method for generating a library design for a set of experiments comprising defining a library array representing an arrangement of experiments in the set of experiments.

In regard to claim 1, Lacy teaches a computer-implemented method and program for generating a library design for a combinatorial library of materials. The library design includes a set of sources representing components to be used in preparing the combinatorial library, destinations representing arrangements of cells and mappings, defining one or more distribution patterns for assigning components to cells in the destination arrangement or arrangements (see abstract).

In regard to claim 2, the invention provides for outputs, in the form of display (abstract and page 5, lines 8-11).

In regard to claim 3, Lacy teaches visual representation of a portion of compositions (page 5, lines 8-11; page 27, lines 21-29).

In regard to claim 6, Lacy teaches mathematical relationships for determining amounts of corresponding source (abstract; page 15, lines 27-31; page 21, lines 21-31 to page 22, lines 1-9).

In regard to claim 7, Lacy teaches mapping of a first group (page 3, lines 7-20).

In regard to claim 8, Lacy teaches mapping of a second group (page 4, lines 10-26).

In regard to claim 9, Lacy teaches a function whereby a source and destination map may be redefined or recalculated, encompassing the remove map defining an amount to be removed (page 4, lines 17-20).

In regard to claim 10, Lacy teaches sources that are defined to interact (page 15, lines 27-31 to page 16, lines 1-7).

In regard to claims 11-13, and 16-22, Lacy teaches that computer program product encompassing all of the limitations recited above in claims 1-3 and 6-10. The program product is taught in the abstract and at page 7, beginning line 8).

In regard to claims 23 and 24, Lacy teaches using the design to perform experiments at figure 4 (synthesis).

Response to Applicant's Arguments

1. Applicant argues that, "the present claims recite that the maps are ordered to define a mapping sequence, and that the amounts specified by the library design are defined at least in part by the order of maps in the mapping sequence". Applicant states that "Lacy does describe mappings that define distribution patterns for assigning components to cells in a destination arrangement or library, in which mapping defines the amount of a component to be assigned to a given cell based, for example, on a gradient set of equations specified by mapping". Applicant argues that "Lacy does not disclose that such mappings can be ordered to define a sequence such that the amounts are defined by the order of multiple mappings, as opposed to the distribution patterns defined within individual mappings. That is, Lacy discloses the calculation of amounts

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based on the contents of mappings, while the present claims specify that amounts are defined at least in part based on ordered relationships between mappings”.

The arguments have been considered but are not deemed persuasive. Firstly, the claims do not specify that the amounts are defined based on ordered *relationships between mappings*.

The claims state that “the amounts being defined at least in part by the order of maps in the mapping sequence. This is not the same as “relationships between maps”. In that regard, Lacy does teach the following at least at page 3, lines 6-20:

In general, in one aspect, the invention features a computer-implemented method for generating a library design for a combinatorial library of materials. The method includes defining one or more sources and one or more destinations, receiving an input defining a first mapping, using the first mapping to calculate a composition of one or materials assigned to one or more of cells of the destination, and generating a data file defining the library design. Each source is electronic data representing a component to be used in preparing the combinatorial library. Each destination is electronic data representing an arrangement of cells. The first mapping is electronic data defining a distribution pattern for assigning a component to cells in the arrangement. The distribution pattern includes a minimum and a maximum amount of the component to be assigned to any cell of the arrangement and a gradient to be applied between the minimum and maximum amounts of the component across the cells. The data file includes electronic data representing the sources, the destinations and the mapping.

Therefore, Lacy teaches that the order (distribution) of maps defines amounts of sources to be applied to the library.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Lori A. Clow
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PRIMARY EXAMINER
9/15/07